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Proposed Maximum Residue Limit PMRL2018-14

Iprodione

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) granted continued registration of products containing iprodione for sale and use in Canada.

Before registering a pesticide for food use in Canada or allowing for continued registration, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made fro.

The dietary assessment for iprodione was published in the PRVD2016-09. PMRA had proposed the cancellation of all food and feed uses and the revocation of all Canadian MRLs due to dietary risks of concern. Based on the comments received through the consultation process, the dietary risk assessment was revised to include only agricultural crop uses that did not pose risk concerns from the drinking water route (that is, greenhouse cucumber, greenhouse lettuce, greenhouse tomato and potato seed-piece treatment for table and processed potatoes) as well as commodities for which importation continues to be permitted (almond, blackberry, carrot, cottonseed, field cucumber, grape, kiwifruit, loganberry, field tomato and raspberry).

The final re-evaluation decision for iprodione (RVD2018-16) indicated that the continued use of this active ingredient on the registered and imported crops listed above has value and the human health and environmental risks associated with these uses are acceptable. However, as indicated in RVD2018-16, the risks from exposure to iprodione residues in/on any other treated crop at the current established MRL level or at 0.1 ppm (as prescribed in Division B.15.002(1) of the Food and Drug Regulations), exceeded PMRA's level of concern. Therefore, MRLs on treated food commodities other than undelinted cottonseeds, kiwifruit, raisins, tomatoes, almond nuts, carrot roots, head and leaf lettuce, blackberries, loganberries, grapes, cucumbers, raspberries and wild raspberries are being proposed to be set at the limit of quantitation of the enforcement analytical method of 0.07 ppm. Further to this, the MRL of 5 ppm for wine will no longer be required as residues in wine, and all other processed commodities derived from grapes, except raisins, shall be covered by the grape MRL of 10 ppm, as specified on the Maximum Residue Limits for Pesticides webpage.

Consultation on the proposed MRLs for iprodione for potatoes, previously subject to the 0.1 ppm MRL of the FDR, is being conducted via this document (see Next Steps, the last section of this document). This document is also being used to inform domestic and international stakeholders of PMRA's decision to set MRLs at the limit of quantitation of the enforcement analytical method of 0.07 ppm for all treated food crops other than undelinted cottonseeds, kiwifruit, raisins, tomatoes, almond nuts, carrot roots, head and leaf lettuce, blackberries, loganberries, grapes, cucumbers, raspberries and wild raspberries due to risks from exposure to iprodione residues in/on these treated food commodities.

A summary of the field trial data used to support the proposed MRL on potatoes can be found in Appendix I and in RVD2018-16.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to replace or be added to the MRLs already established for iprodione, are as follows.

Table 1 Proposed Maximum Residue Limits for Iprodione

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Iprodione	3-(3,5-dichlorophenyl)-*N*-isopropyl-2,4-dioxoimidazolidine-1-carboximide[2]	10[3]	Grapes
		0.07[4]	Potatoes, all food crops (other than those listed in this item)

[1] ppm = parts per million

[2] This residue definition is being proposed to replace the current residue definition for all food crops, as iprodione per se, is a sufficient marker compound for enforcement purposes.

[3] The current MRL of 5 ppm on wine is proposed to be covered by the grape MRL of 10 ppm, as specified on the Maximum Residue Limits for Pesticides webpage.

[4] This MRL is proposed to replace the currently established MRLs of 13 ppm for leeks; 11 ppm for mustard greens; 10 ppm for nectarines and peaches; 5 ppm for strawberries and cherries; 4 ppm for ginseng roots; 3 ppm for apricots; 2 ppm for fresh prune plums, plums, and dry and edible-podded beans; 1 ppm for rapeseeds (canola); and 0.2 ppm for dry bulb onions.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for iprodione in Canada with corresponding American tolerances and Codex MRLs[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Index webpage, by pesticide or commodity.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Potatoes	0.07	0.5	Not established
All food crops (other than those listed in this item)	0.07	Not established[1]	Not established[1]

[1] There are specific American tolerances and/or Codex MRLs established in various food commodities, but none for "all food crops" as proposed by Canada.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for iprodione up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data for iprodione in potatoes were re-assessed to support the continued domestic registration of iprodione on this crop as a result of the re-evaluation of this active ingredient.

Maximum Residue Limits

The recommendation for the maximum residue limit (MRL) for iprodione was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for potatoes.

Table A1 Summary of Field Trial Data Used to Support the MRL

Commodity	Application Method/ Total Application Rate (g a.i./100 kg seed)[1]	Preharvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)	Experimental Processing Factor
Potatoes	Potato seed-piece treatment/ 9.7-10.3	74-127	<0.01	<0.01	No quantifiable residues at exaggerated rates.

[1] g a.i./100 kg seed = grams of active ingredient per 100 kilograms of treated seeds

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of iprodione. Residues of iprodione in potato commodities at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.